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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO
10/628,345	05/21/2004	Giovina DiMateeo-Leggio	4477	
7590 12/02/2004			EXAMINER	
GIOVINA INTERNATIONAL INC. OF AMERICA			FLOOD, MICHELE C	
SUITE 807 19495 BISCAYNE BLVD.			ART UNIT	PAPER NUMBER
AVENTURA, FL. 33180			1654	

DATE MAILED: 12/02/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

	A series No	A P (/ a)				
	Application No.	Applicant(s)				
	10/628,345	DIMATEEO-LEGGIO, GIOVINA				
Office Action Summary	Examiner	Art Unit				
	Michele Flood	1654				
The MAILING DATE of this communication appears on the cover sheet with the correspondence address Period for Reply						
A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION. - Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication. - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely. - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication. - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).						
Status						
1) Responsive to communication(s) filed on 05 M	av 2004.					
3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under <i>Ex parte Quayle</i> , 1935 C.D. 11, 453 O.G. 213.						
Disposition of Claims	,					
4) Claim(s) 1 is/are pending in the application. 4a) Of the above claim(s) is/are withdray 5) Claim(s) is/are allowed. 6) Claim(s) 1 is/are rejected. 7) Claim(s) is/are objected to. 8) Claim(s) are subject to restriction and/or	·.					
9) The specification is objected to by the Examiner.						
10)☐ The drawing(s) filed on is/are: a)☐ accepted or b)☐ objected to by the Examiner.						
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).						
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d). 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.						
Priority under 35 U.S.C. § 119						
12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f). a) All b) Some * c) None of: 1. Certified copies of the priority documents have been received. 2. Certified copies of the priority documents have been received in Application No. 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)). * See the attached detailed Office action for a list of the certified copies not received.						
Attachment(s) 1) Notice of References Cited (PTO-892) Notice of Profesorous's Petrot Proving Parism (PTO 048)	4)					
Notice of Draftsperson's Patent Drawing Review (PTO-948) Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date		atent Application (PTO-152)				

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DETAILED ACTION

Specification/Abstract

Applicant is reminded of the proper content of an abstract of the disclosure.

A patent abstract is a concise statement of the technical disclosure of the patent and should include that which is new in the art to which the invention pertains. If the patent is of a basic nature, the entire technical disclosure may be new in the art, and the abstract should be directed to the entire disclosure. If the patent is in the nature of an improvement in an old apparatus, process, product, or composition, the abstract should include the technical disclosure of the improvement. In certain patents, particularly those for compounds and compositions, wherein the process for making and/or the use thereof are not obvious, the abstract should set forth a process for making and/or use thereof. If the new technical disclosure involves modifications or alternatives, the abstract should mention by way of example the preferred modification or alternative.

The abstract should not refer to purported merits or speculative applications of the invention and should not compare the invention with the prior art.

Where applicable, the abstract should include the following:

- (1) if a machine or apparatus, its organization and operation;
- (2) if an article, its method of making;
- (3) if a chemical compound, its identity and use;
- (4) if a mixture, its ingredients;
- (5) if a process, the steps.

Extensive mechanical and design details of apparatus should not be given.

In the instant case, the abstract is generally narrative, and is vague and indefinite as to the subject matter Applicant intends to direct the invention.

Line 1 of the abstract recites, "HEALTHY PROSTATE FORMULA", which appears to be a name or trademark of a composition. The use of trademarks in the abstract should be avoided. See the rejection made under 35 U.S.C. 112, 2nd paragraph for further clarification for the use of trademarks in an application.

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The following guidelines illustrate the preferred layout for the specification of a utility application. These guidelines are suggested for the applicant's use.

Arrangement of the Specification

As provided in 37 CFR 1.77(b), the specification of a utility application should include the following sections in order. Each of the lettered items should appear in upper case, without underlining or bold type, as a section heading. If no text follows the section heading, the phrase "Not Applicable" should follow the section heading:

- (a) TITLE OF THE INVENTION.
- (b) CROSS-REFERENCE TO RELATED APPLICATIONS.
- (c) STATEMENT REGARDING FEDERALLY SPONSORED RESEARCH OR DEVELOPMENT.
- (d) INCORPORATION-BY-REFERENCE OF MATERIAL SUBMITTED ON A COMPACT DISC (See 37 CFR 1.52(e)(5) and MPEP 608.05. Computer program listings (37 CFR 1.96(c)), "Sequence Listings" (37 CFR 1.821(c)), and tables having more than 50 pages of text are permitted to be submitted on compact discs.) or

REFERENCE TO A "MICROFICHE APPENDIX" (See MPEP § 608.05(a). "Microfiche Appendices" were accepted by the Office until March 1, 2001.)

- (e) BACKGROUND OF THE INVENTION.
 - (1) Field of the Invention.
 - (2) Description of Related Art including information disclosed under 37 CFR 1.97 and 1.98.
- (f) BRIEF SUMMARY OF THE INVENTION.
- (g) BRIEF DESCRIPTION OF THE SEVERAL VIEWS OF THE DRAWING(S).
- (h) DETAILED DESCRIPTION OF THE INVENTION.
- (i) CLAIM OR CLAIMS (commencing on a separate sheet).
- (j) ABSTRACT OF THE DISCLOSURE (commencing on a separate sheet).
- (k) SEQUENCE LISTING (See MPEP § 2424 and 37 CFR 1.821-1.825. A "Sequence Listing" is required on paper if the application discloses a nucleotide or amino acid sequence as defined in 37 CFR 1.821(a) and if the required "Sequence Listing" is not submitted as an electronic document on compact disc).

Content of Specification

(a) <u>Title of the Invention</u>: See 37 CFR 1.72(a) and MPEP § 606. The title of the invention should be placed at the top of the first page of the specification unless the title is provided in an application data sheet. The title of the invention should be brief but technically accurate and descriptive, preferably from two to seven words may not contain more than 500 characters.

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- (b) <u>Cross-References to Related Applications</u>: See 37 CFR 1.78 and MPEP § 201.11.
- (c) <u>Statement Regarding Federally Sponsored Research and Development:</u> See MPEP § 310.
- (d) Incorporation-By-Reference Of Material Submitted On a Compact Disc:
 The specification is required to include an incorporation-by-reference of electronic documents that are to become part of the permanent United States Patent and Trademark Office records in the file of a patent application. See 37 CFR 1.52(e) and MPEP § 608.05. Computer program listings (37 CFR 1.96(c)), "Sequence Listings" (37 CFR 1.821(c)), and tables having more than 50 pages of text were permitted as electronic documents on compact discs beginning on September 8, 2000.

Or alternatively, Reference to a "Microfiche Appendix": See MPEP § 608.05(a). "Microfiche Appendices" were accepted by the Office until March 1, 2001.

- (e) <u>Background of the Invention</u>: See MPEP § 608.01(c). The specification should set forth the Background of the Invention in two parts:
 - (1) Field of the Invention: A statement of the field of art to which the invention pertains. This statement may include a paraphrasing of the applicable U.S. patent classification definitions of the subject matter of the claimed invention. This item may also be titled "Technical Field."
 - (2) Description of the Related Art including information disclosed under 37 CFR 1.97 and 37 CFR 1.98: A description of the related art known to the applicant and including, if applicable, references to specific related art and problems involved in the prior art which are solved by the applicant's invention. This item may also be titled "Background Art."
- (f) Brief Summary of the Invention: See MPEP § 608.01(d). A brief summary or general statement of the invention as set forth in 37 CFR 1.73. The summary is separate and distinct from the abstract and is directed toward the invention rather than the disclosure as a whole. The summary may point out the advantages of the invention or how it solves problems previously existent in the prior art (and preferably indicated in the Background of the Invention). In chemical cases it should point out in general terms the utility of the invention. If possible, the nature and gist of

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- the invention or the inventive concept should be set forth. Objects of the invention should be treated briefly and only to the extent that they contribute to an understanding of the invention.
- (g) <u>Brief Description of the Several Views of the Drawing(s)</u>: See MPEP § 608.01(f). A reference to and brief description of the drawing(s) as set forth in 37 CFR 1.74.
- (h) Detailed Description of the Invention: See MPEP § 608.01(g). A description of the preferred embodiment(s) of the invention as required in 37 CFR 1.71. The description should be as short and specific as is necessary to describe the invention adequately and accurately. Where elements or groups of elements, compounds, and processes, which are conventional and generally widely known in the field of the invention described and their exact nature or type is not necessary for an understanding and use of the invention by a person skilled in the art, they should not be described in detail. However, where particularly complicated subject matter is involved or where the elements, compounds, or processes may not be commonly or widely known in the field, the specification should refer to another patent or readily available publication which adequately describes the subject matter.
- (i) Claim or Claims: See 37 CFR 1.75 and MPEP § 608.01(m). The claim or claims must commence on separate sheet or electronic page (37 CFR 1.52(b)(3)). Where a claim sets forth a plurality of elements or steps, each element or step of the claim should be separated by a line indentation. There may be plural indentations to further segregate subcombinations or related steps. See 37 CFR 1.75 and MPEP § 608.01(i)-(p).
- (j) Abstract of the Disclosure: See MPEP § 608.01(f). A brief narrative of the disclosure as a whole in a single paragraph of 150 words or less commencing on a separate sheet following the claims. In an international application which has entered the national stage (37 CFR 1.491(b)), the applicant need not submit an abstract commencing on a separate sheet if an abstract was published with the international application under PCT Article 21. The abstract that appears on the cover page of the pamphlet published by the International Bureau (IB) of the World Intellectual Property Organization (WIPO) is the abstract that will be used by the USPTO. See MPEP § 1893.03(e).
- (k) <u>Sequence Listing.</u> See 37 CFR 1.821-1.825 and MPEP §§ 2421-2431. The requirement for a sequence listing applies to all sequences disclosed in a given application, whether the sequences are claimed or not. See MPEP § 2421.02.

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An examination of this application reveals that applicant is unfamiliar with patent prosecution procedure. While an inventor may prosecute the application, lack of skill in this field usually acts as a liability in affording the maximum protection for the invention disclosed. Applicant is advised to secure the services of a registered patent attorney or agent to prosecute the application, since the value of a patent is largely dependent upon skilled preparation and prosecution. The Office cannot aid in selecting an attorney or agent.

Applicant is advised of the availability of the publication "Attorneys and Agents Registered to Practice Before the U.S. Patent and Trademark Office." This publication is for sale by the Superintendent of Documents, U.S. Government Printing Office, Washington, D.C. 20402.

The disclosure of the specification is objected to because of the following informalities:

The specification appears to contain an oath of declaration. The oath of declaration is not to be included in the specification. Appropriate correction is required.

The specification, at page 1, lines 6-8, under "<u>DETAILED DESCRIPTION OF</u>

<u>HEALTHY PROSTATE FORMULA</u>", recites the sentence, "Healthy Prostate Formula is packaged in blue PETE bottles of 150 tablets with a 'black child resistant cap' and silver foil label with blue print." The phrase 'black child resistant cap' may be construed as having more than one meaning, wherein one meaning may be offensive to certain ethnic groups of people. It would appear that the recitation of 'black child resistant cap'

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is used by Applicant to set forth the color of the cap of the bottle. To avoid misinterpretation of the phrase, it is suggested that Applicant avoid use of the phrase as recited and that Applicant replace the aforementioned sentence with Healthy Prostate

Formula is packaged in blue PETE bottles of 150 tablets with a black cap that is child-resistant and a (or with a) silver foil label with blue print.

Abbreviations in the first instance of the specification should be expanded upon with the abbreviation indicated in parentheses. In the instant case, the specification on page 1, line 6, recites the abbreviation "PETE"; however, it is unclear as to what the abbreviation "PETE" stands for. Applicant may overcome the objection by setting forth the meaning of an abbreviation as set forth in the following example: "United States Patent and Trademark Office (USPTO)".

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 1 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The claim is generally narrative and indefinite, failing to conform to current U.S. practice. Claims must be only one sentence long and must be numbered. Claims must also be directed to one category of invention. For example, categories of invention are a composition, a method of making a composition, and a method of using a

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composition. For examples of proper claim language, please see the following *patents. See U.S. Patent No. 6,093,404 for an example of proper claim language for a composition claim. See U.S. Patent No. 6,713,092 for an example of proper claim language for a method of making a composition. See U.S. Patent No. 6,193,978 for an example of proper claim language for a method of using a therapeutic composition.

Applicant should avoid the use of the phrase "I claim that our Healthy Prostate Formula" because the use of such language fails to conform to U.S. practice.

The metes and bounds of Claim 1 are rendered uncertain by the phrase "Healthy Prostate Formula" because it is unclear as to the subject matter Applicant intends to direct the invention. For instance, while Applicant has defined the functional effects of the claim-designated, it is unclear as to what are the ingredients or active agents comprising the claim-designated formula or the basic chemical core of the instantly claimed composition. For product claims, the claim limitations should define discrete physical structures or materials. In the instant case, the metes and bounds of the claims are rendered vague and indefinite because the subject matter of Claim 1 has not been properly construed by terms that limit its scope. For example, as drafted, the terms defining the instantly claimed composition of Claim 1 is nebulous at best. Defining a composition by reciting its functional activities (e.g., alleviates symptoms of benign prostatic hyperplasia, etc.) without defining the ingredients or active agents or fundamental chemical core or chemical structure of the composition fails to distinguish it from another substance. A substance may be identified by its physical and chemical properties and by its composition because no two substances are alike in all respects.

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Therefore, a proper search of the claim is precluded because an initial analysis of the claim by the Examiner finds that the boundaries of the protection sought by Applicant cannot be identified and it is not understood how the claim relates to and defines what the Applicant has indicated is the invention. Hence, Claim 1 as drafted, fails to satisfy the requirement of 35 U.S.C. that the specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which Applicant regards as his or her invention.

Claim 1, line 1, recites the phrase "Healthy Prostate Formula", in line 1 of the claim, which appears to be a trademark. It is also noted that the phrase is recited throughout the application, including the title, specification and abstract. If "Healthy Prostate Formula" is a trademark, the use of trademark renders a claim vague because the relationship between a trademark and the product it identifies is often indefinite, uncertain, and arbitrary. The formula or characteristics of the product may change from time to time and yet it may continue to be sold under the same trademark. In patent specifications, every element or ingredient of the product should be set forth in positive, exact, intelligible language, so that there will be no uncertainty as to what is meant.

Arbitrary trademarks which are liable to mean different things at the pleasure of manufacturers do not constitute such language. Ex Parte Kattwinkle, 12 USPQ 11 (Bd. App. 1931). Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner which might adversely affect their validity as trademarks. It is

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suggested that each letter of the trademark be capitalized or include a proper trademark symbol, such as ™ or ®.

* Applicant is advised that the <u>cited</u> U.S. patents and patent application publications are available for download via the Office's PAIR. As an alternate source, <u>all</u> U.S. patents and patent application publications are available on the USPTO web site (<u>www.uspto.gov</u>), from the Office of Public Records and from commercial sources. Should you receive inquiries about the use of the Office's PAIR system, applicants may be referred to the Electronic Business Center (EBC) at http://www.uspto.gov/ebc/index.html or 1-866-217-9197.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michele Flood whose telephone number is 571-272-0964. The examiner can normally be reached on 7:00 am - 3:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell can be reached on 571-272-0974. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

PATENT EXAMINER

MCF

November 29, 2004